QI Follow Up Meeting

December 14, 2007 9 am – 10:30 am Room 133

Meeting Minutes

1. **Update from Directors and Supervisors**
   a. Status of department meetings
   b. Progress / design of the lab's QI project

Dr. Han and Supervisors: Peter Belanger, Rozelta Boyd, Tracy Stiles, Bob Goldbaum, Donghui Liu, Paul Elvin, Judy Westerling, Arthur Kazianis

Julie Nassif and Supervisors: Felipe Alfonso, Peter Kane, Paul Servizio, Jill Clemmer, Jennifer Jenner, Chuck Salemi

Kathy Nawn

Betsy Szymczak and Supervisor: Cheryl Gauthier

Sandy Smole and Supervisors: Raimond Konomi, Karen Chen, Scott Hennigan, Glenn Krumholz, Xingtai Wang

Minutes:
Each Laboratory Division described recent meetings that have been held within their units. The Divisions are in various stages of transition to the new QA/QI model. All have made progress.

2. **Flow of Documents**
   (please bring email dated 11/8/07 from Peggy and the Records Review Schedule Chart)
   a. Review chart
   b. Review email dated November 8, 2007, subject: update on flow of documents
   c. Review QA Reporting Coversheet
   d. Review In process Review Form
   e. Questions / comments

Minutes:
The documents listed above were distributed and discussed. Monthly, the Technical Supervisor and the Lab Division Director will review the various documents listed on the Chart. The review of these documents will be documented on the QA Reporting Coversheet. Each month, about mid-month, the Laboratory Division Directors will bring these forms to the Division Directors meeting. At this meeting they can discuss any outstanding issues. Dr. Gilchrist will sign these forms at this meeting and there will be no additional exchange of these forms. This form ensures compliance with the CLIA regulations.

The handouts include a footer section that describes when to use the form and where the form can be found on the common drive.

There was discussion relative to the old problem logs. These were added to the revised Records Review Chart. They are to be reviewed monthly. Several labs requested that the old problem tally log be posted on the f common drive. This will be posted along with other documents.

The Supervisors asked that the old Annual Records Review Schedule be posted on the F common drive. This will be posted along with additional documents.

A request was made to post on the F drive the QA Tracking sheets that are maintained to track documents that are submitted to QA and Dr. Gilchrist. This posting will enable Lab Supervisors and Directors to view the status of the documents submitted. Peggy has been revising the QA tracking sheet and when it is in better shape it may be possible to post it as a read only file. In the meantime, if you are wondering the status of a document, either send an email or call Peggy at ext. 6243. A request was also made to assign a tracking number to each document submitted to QA. The tracking number, although a good idea, will add another layer without improving the flow of documents.

3. Revised Corrective action Form

a. Distribute form
b. Explain form: when to use, how it will be tracked, reviewers
c. Questions / comments

Minutes:
The new Corrective action form was distributed and discussed. There was discussion regarding how to differentiate a problem from a corrective action. The corrective action form describes what types of incidences should be documented on the form. Issues with run sheets may be documented on the problem log, but in some cases may warrant being documented as a corrective action. We did discuss several types of incidences and criteria that should be used to differentiate between the two. We agreed that for the January meeting, the Supervisors and Directors labs should be bring examples of problems documented either on the problem log or on run sheets. We will use these examples, along with some criteria to sort out problems versus corrective actions.

4. Quality Assurance Studies / Quality Improvement Projects

a. distribute summaries of QA study projects by labs for past few years
b. distribute a copy of the QA study project outline used in past years

Minutes:
Handouts distributed included the QA Study project outline and lists of the QA Study Projects for 2005, 2006 and 2007. The names of the labs are included as a reference only. If a lab identifies a QA study project that looks of interest, they will know what lab to contact to get additional information. These lists may also provide ideas of projects for some labs.

5. Management Reports to be generated by IT

a. Frequency, distribution and review of the management reports
b. Corrected reports
c. Number of unsatisfactory specimens
d. Transit times for specimens

Minutes:
Discussed how data from these various reports can be used by the laboratory to identify areas for improvement. Supervisors and Directors were asked to identify additional data that may be helpful.

6. General Discussion

A. Artel pipette calibration system:

1. Request was made for a training session since new staff is assigned to perform pipette calibration in several labs. Peggy will make arrangements for training sessions after the first of the year.
2. There was a question regarding a cost analysis of the Artel system. A cost analysis was done back in 2005. At that time, based on the number of pipettes at the various volumes and the cost of reagents, it was determined that the Artel system would be used for pipette with volumes of 200 ul or less. The Artel system was purchased after Laboratory Supervisors stated that they could not achieve accurate and consistent calibration results for pipettes set to deliver volumes less than 50 ul using a gravimetric calibration method.
   During this discussion, the Analytical Laboratory Supervisor stated that they have been using the gravimetric method for small volume pipettes and have been able to obtain good accuracy and consistency. At the next meeting the Analytical Laboratory Supervisor will bring some data and describe the type of balance they use for the gravimetric calibration.

B. PT self evaluation forms

The Proficiency self evaluation form needs to be completed any time a PT sample isn't graded. The reasons samples aren't graded can vary and may include: a lack of consensus of results, committee decision, results not submitted on time for evaluation, method listed not evaluated. Since PT survey results go through QA, QA will initiate these forms most of the time. If a lab receives the results directly from the PT company, the lab should initiate the self evaluation form. At next month's meeting, we will review the PT self evaluation form. Peggy is thinking of revising the form to make it to a one page document. Both the current and the revised form will be presented at the next meeting.

C. Some of the CDC/LRN surveys have their own documentation requirements, similar to our corrective action forms for missed PT samples. In these situations, should the labs complete the in-house corrective forms as well? Based on the discussion, it appears that the CDC or LRN corrective action form is very similar to our in house form. Since this seems redundant, the labs should use the forms required by CDC/LRN and submit them to QA. QA will assign the corrective action a tracking number and then make a notation in the tracking database that the CDC or LRN form was completed.

D. Additional discussion of problem log versus corrective action. This will be a topic for discussion at the January meeting. Lab Supervisors should bring examples of issues that were identified during the record reviews for the months of November and December. We can use these examples to discuss some criteria that may be used to assist us in differentiated a problem from a corrective action. Some of the criteria include the frequency of the occurrence and the impact on patient testing or results.

E. Lab audits will continue with more frequency and regularity in 2008. At the January meeting we will discuss the SOP, QA.010, Laboratory Audits.